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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,860	11/05/2001	Gust H. Bardy	032580.0042.CIP	6000

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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/011,860

Applicant(s)

BARDY ET AL.

Examiner

Kristen L Droesch

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 7-8, 12-13, 17-19, 23-24, 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmstrom (5,391,191).

Regarding claims 1 and 17, Holmstrom shows a power supply or voltage output system comprising a capacitor subsystem (8) and a battery subsystem (6) electrically coupled to the capacitor subsystem (Col. 4, lines 34-37).

With respect to claims 2-3, and 18-19, Holmstrom shows the pacing energy comprises a monophasic waveform (41) having a peak voltage that is approximately 0.1 Volts to approximately 100 Volts, and approximately 0.1 Volts to approximately 25 Volts (Col. 9, lines 3-61; Figs. 2, 5).

Regarding claims 7-8, and 23-24, Holmstrom shows the pacing energy comprises a monophasic waveform (41) having a pulse width that is approximately 1 millisecond to approximately 40 milliseconds, and approximately 1 millisecond to approximately 10 milliseconds (Col. 6, lines 11-16, and 54-58).

Art Unit: 3762

With respect to claims 12-13, and 28-29, Holmstrom shows the pacing energy comprises a monophasic waveform (41) comprising a negative waveform with a tilt of approximately 5% to approximately 95% (Fig. 2).

3. Claims 1, 17, 33, 49, and 65-69 are rejected under 35 U.S.C. 102(e) as being anticipated by KenKnight (6,148,230).

With respect to claims 1, 17, and 33, KenKnight shows an ICD comprising a housing having an electrically conductive surface on an outer surface of the housing; a lead assembly (20) coupled to the housing which does not directly contact the patient's heart or reside in the intrathoracic blood vessels; a capacitor subsystem located within the housing and electrically coupled to the electrically conductive surface of the electrode and a battery subsystem electrically coupled to the capacitor subsystem (Col. 1, lines 49-58; Col. 3, lines 60-62; Col. 4, lines 25-28 and 42-50).

Regarding claim 49, KenKnight shows a method for supplying power for an ICD comprising generating pacing energy, storing pacing energy, and delivering pacing energy to a patient's heart (Col. 1, lines 49-58; Col. 3, lines 60-62; Col. 4, lines 25-28 and 42-50). The introductory statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 65-69, the statements regarding the subcutaneous positioning of the ICD between the third and fifth ribs, fourth and sixth ribs, sixth and eighth ribs, eighth and tenth ribs and tenth and twelfth ribs have not been considered since the statements only modify the introductory statement of intended use. The KenKnight ICD could be positioned in any of these locations if desired.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-6, 9-11, 14, 20-22, 25-27, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmstrom (5,391,191).

Regarding claims 4-6, and 20-22, Holmstrom discloses the claimed invention except for the monophasic waveform having a peak voltage of approximately 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, and approximately 75 Volts to approximately 100 Volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform peak voltage as taught by Holmstrom with the monophasic waveform peak voltages of 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, and approximately 75 Volts to approximately 100 Volts, since applicant has not disclosed that these particular monophasic waveform peak voltages provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform peak voltage such as 2.5 Volts, or 5.0 Volts taught by Holmstrom for pacing the heart.

With respect to claims 9-11, and 25-27, Holmstrom discloses the claimed invention except for the monophasic waveform having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40

Art Unit: 3762

milliseconds. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform pulse width as taught by Holmstrom with monophasic waveforms having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds, since applicant has not disclosed that these particular monophasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform pulse width such as approximately 1 millisecond as taught by Holmstrom for applying pacing pulses.

Regarding claims 14, and 30, Holmstrom discloses the claimed invention except for the monophasic waveform having a tilt of 50%. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the tilt of the monophasic waveform as taught by Holmstrom with a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any tilt such as the 5% to 90% tilt taught by Holmstrom for applying pacing pulses.

6. Claims 15-16, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmstrom (5,391,191) in view of Florio et al. (6,519,493). Holmstrom is as explained before. Although Holmstrom fails to show the monophasic pacing pulses are applied at a rate of approximately 20 to approximately 120 beats per minute, attention is directed to Florio et al. who teaches that pacing the heart at a rate of 60-80 bpm in order to prevent the heart from beating too slowly (Col. 1, lines 31-40). Therefore, it would have been obvious to one with ordinary skill in

Art Unit: 3762

the art at the time the invention was made to apply the monophasic pacing pulses of Holmstrom at a rate of 60-80 bpm in order to prevent the heart from beating too slowly.

Regarding claims 16, and 32, although Holmstrom and Florio et al. fail to specifically point out that the pacing is applied after a patient's heart rate is equal or less than approximately 20 beats/minute, it is well known that pacing pulses are applied when a heart beat less than 50 or 60 bpm is detected. See Schaldach et al. (4,412,541; Col. 9, lines 12-17), and Baker et al. (5,261,401; Col. 2, lines 47-51) for example. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply pacing to a patient's heart when the rate when it is equal or less than approximately 20 beats/minute.

7. Claims 34-35, 39-40, 44-45, 50-51, 55-56, and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Holmstrom (5,391,191). Although KenKnight fails to show utilizing monophasic pacing pulses, attention is directed to Holmstrom who shows utilizing monophasic pacing pulses having a negative polarity, a tilt of approximately 5% to approximately 90%, and a peak voltage of approximately 0.1 Volts to approximately 100 Volts and approximately 0.1 Volts to approximately 25 Volts and a duration of approximately 1 millisecond to approximately 40 milliseconds and approximately 2 milliseconds to approximately 10 milliseconds, (Col. 4, lines 34-37; Col. 6, lines 11-16, and 54-58; Col. 9, lines 3-61; Figs. 2, 5). Holmstrom teaches that utilizing a monophasic waveform stimulation pulses consumes half the current that biphasic stimulation pulses of the same amplitude and duration consume (Col. 6, lines 40-68). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize monophasic pacing pulses having a negative polarity and a peak voltage of approximately 0.1 Volts to approximately 100 Volts and

Art Unit: 3762

approximately 0.1 Volts to approximately 100 Volts and a duration of approximately 1 millisecond to approximately 40 milliseconds and approximately 2 milliseconds to approximately 10 milliseconds as Holmstrom teaches since utilizing a monophasic waveform stimulation pulses consumes half the current that biphasic stimulation pulses of the same amplitude and duration consume.

8. Claims 36-38, 41-43, 46-48 52-54, 57-59 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Holmstrom (5,391,191).

KenKnight and Holmstrom are as explained before.

Regarding claims 36-38, and 52-54, KenKnight and Holmstrom disclose the claimed invention except for the monophasic waveform has a peak voltage of approximately 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, and approximately 75 Volts to approximately 100 Volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform peak voltage as taught by KenKnight and Holmstrom with monophasic waveform peak voltages of 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, and approximately 75 Volts to approximately 100 Volts since applicant has not disclosed that these particular monophasic waveform peak voltages provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform peak voltage such 2.5 Volts, or 5.0 Volts taught by KenKnight and Holmstrom for pacing the heart.

With respect to claims 41-43, and 57-59 KenKnight and Holmstrom discloses the claimed invention except for the monophasic waveform having a pulse width between

Art Unit: 3762

approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform pulse width as taught by KenKnight and Holmstrom with monophasic waveforms having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds, since applicant has not disclosed that these particular monophasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform pulse width such as approximately 1 millisecond as taught by KenKnight and Holmstrom for applying pacing pulses.

Regarding claims 46, and 62, KenKnight and Holmstrom disclose the claimed invention except for the monophasic waveform having a tilt of 50%. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the tilt of the monophasic waveform as taught by KenKnight and Holmstrom with a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any tilt such as the 5% to 90% tilt taught by KenKnight and Holmstrom for applying pacing pulses.

9. Claims 47-48, 63, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Holmstrom (5,391,191) and further in view of Florio et al. (6,519,493). KenKnight and Holmstrom is as explained before. Although KenKnight and

Art Unit: 3762

Holmstrom fail to shows the monophasic pacing pulses are applied at a rate of approximately 20 to approximately 120 beats per minute, attention is directed to Florio et al. who teaches that pacing the heart at a rate of 60-80 bpm in order to prevent the heart from beating too slowly (Col. 1, lines 31-40). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the monophasic pacing pulses of KenKnight and Holmstrom at a rate of 60-80 bpm in order to prevent the heart from beating too slowly.

Regarding claims 48, and 64, although KenKnight, Holmstrom and Florio et al. fail to specifically point out that the pacing is applied after a patient's heart rate is equal or less than approximately 20 beats/minute, it is well known that pacing pulses are applied when a heart beat less than 50 or 60 bpm is detected. See Schaldach et al. (4,412,541; Col. 9, lines 12-17), and Baker et al. (5,261,401; Col. 2, lines 47-51) for example. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply pacing to a patient's heart when the rate when it is equal or less than approximately 20 beats/minute.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3762

11. Claims 1-14, 17- 30, 33-46, 49-62, and 66-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 21-34, 41-54, 61-74, and 81-84 of copending Application No. 10/011958. Claims 1, 7-12, 33, 40-44, 49, and 55-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 26-37, 75, 100-112, and 137-148 of copending Application No. 10/015202. Although the conflicting claims are not identical, they are not patentably distinct from due to the fact that the only claimed difference is intended use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sanchez-Zambrano (5,895,414) shows the implantation location of an implantable cardiac device between the third and fifth ribs.

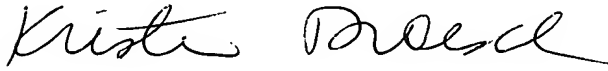
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

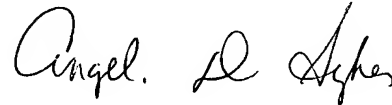
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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